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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,082	09/24/2001	Wei-Sing Chu	2313-113	1159
6449	7590	01/08/2004	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			SPIEGLER, ALEXANDER H	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SMA

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/869,082	CHU, WEI-SING	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 20 December 2002.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 20-36 is/are pending in the application.

4a) Of the above claim(s) 27-36 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 20-26 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### *Status of the Application*

1. This action is in response to Applicants response, filed on October 1, 2003. Currently, claims 27-36 are pending, claims 20-26 are rejected, and claims 27-36 have been withdrawn. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. This action is made FINAL. Any objections and rejections not reiterated below are hereby withdrawn.

### *Election/Restrictions*

2. Applicant affirms the election with traverse, of Group I, claims 20-26, and argues that claims 27-30 should be examined along with Group I, “since they pertain as well to a reaction occurring on a microscope slide, and should thus constitute approximately the same scope of search.” (See Applicants remarks on page 4) Applicants also argue that if Group II is rejoined, than Group III should be rejoined as well. (See Applicants remarks on page 4) Finally, Applicants argue examining claims 20-36 at once is consistent with the PTO’s own goal of compact prosecution. (See Applicants remarks on page 4)

Applicant’s arguments have been considered, but are not persuasive for the following reasons. First, Group I is drawn to a concave coverslip and a method of performing an assay on a biological sample on a microscope slide using said coverslip, whereas Group II drawn to a method of performing an assay on a biological sample using a reaction chamber for processing. That is, Group II is drawn to placing a slide into a reaction chamber for processing. Group I does not require the use of a reaction chamber for processing a reaction. Furthermore, the coverslip used in Group II is not the coverslip of Group I. Accordingly, Groups I-II do not relate

to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the above reasons and those of record. It is also noted that because Group II will not be included in the examination of Group I, Applicants arguments with respect to Group III are not persuasive. Also, Applicant's argument with respect to the PTO's goal of compact prosecution is also not persuasive, since the PTO's goal of compact prosecution does not require examination of more than one invention per application.

Accordingly, the restriction requirement is maintained.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 20, 22-23, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Atwood et al. (USPN 5,364,790).

Atwood teaches a coverslip for a microscope slide where a portion of the coverslip is concave. (see Figs. 1, 2 and 4 and cols. 7-8) Atwood also teaches the combination of a concave coverslip, a microscope slide and an insert of a control sample sandwiched between a portion of said coverslip and said microscope slide. (see Figs. 1, 2 and 4 and cols. 7-8, 16-17). Atwood teaches that the component system comprising the coverslip, microscope slide and reagents (taught above), can be used in performing a PCR reaction. (see columns 5-6 and 10-19).

### **Applicant's Arguments**

Applicants argue Atwood “neither teaches, discloses, nor suggest a concave coverslip enclosing a *known* volume when placed onto a microscope slide” (emphasis added) (See Applicants remarks on page 5). Applicant argues Atwood does not teach a known volume, since the cover is compliant, Atwood teaches the addition of “about” one drop, rather than a known volume, the volume of reagent used by Atwood is chosen to be slightly larger than the volume between the concave surface of the cover, the precise volume of air will not be known, so neither will the volume of reagent left after the air is expelled, Atwood teaches that a small volume of liquid may spill out and that volume is unknown. (See Applicants remarks on pages 5-6)

### **Response to Applicant's Arguments**

Applicant's arguments have been considered, but are not persuasive for the following reasons. First, the claims nor specification do not define what is meant by “known”, and therefore, it is not clear as to whether “known” means that the skilled artisan “known” the volume as soon as the reagent is placed into the microscope slide, right before an assay occurs on the slide, or after an assay occurs on the slide, etc. Furthermore, there is no set definition or parameter as far as to what constitutes how exact or precise the volume must be “known”. For example, when one deposits “about” one drop onto a slide, they “know” there is “about” one drop on the slide. Even if the skilled artisan uses a slightly larger volume than the volume between the concave surface of the cover, they “know” they have placed a larger volume onto the slide, and moreover, they “know” that a small amount may spill out.

Atwood also teaches the following passages, which demonstrate the volume is “known”:

The degree of concavity is *chosen to define the volume of reagent 13* that will be contained between the cover 16 and the slide when the seal ring 20 presses the rim portion 19 of the cover 16 against the slide 14. (col. 7, line 66 to col. 8, line 1)

A pipet set to deliver the *desired reagent volume* is preferably used, by hand, to deliver the reagent as a droplet close to the center of the concave surface. (col. 11, lines 32-34)

Thus, as the rim portion 19 of the cover 16 is compressed to completion, it is preferable for the cover itself to be compliant, so that it can expand to accommodate the *fixed reagent volume* without a large increase in pressure, which otherwise would make assembly difficult. (col. 12, lines 23-28)

In our work, we found that the *optimum reagent quantities* for in situ PCR are different than for PCR in solution. (col. 16, lines 28-30).

(emphasis added)

It is also noted Applicants arguments with respect to the compliant cover is not persuasive, since one reason why the cover should be compliant is avoid braking the slide or cover seal and cause of loss of reagent when the reagent is heated to a temperature approaching or beyond its boiling point (see col. 12, lines 23-43). Additionally, Applicants arguments with respect the spilling of an unknown volume of liquid is also not persuasive, since the claims do not require such a limitation. Accordingly, for these reasons and those of record, the rejection is maintained.

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 21 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atwood et al. (USPN 5,364,790) as applied to claims 20, 22-23, 25 and 27 above, and further in view of Pan et al. (WO 97/07241).

The teachings of Atwood are presented above. Specifically, Atwood teaches a concave cover slip, which can be used in a PCR reaction. Atwood does not teach a coverslip comprising reagents dried thereon.

However, drying reagents onto coverslips is well known in the art. For example, Pan teaches a PCR reaction comprising attaching a tissue section onto a coverslip, drying the tissue, and then adding reagents to carry out the PCR reaction (pg. 3-10 and example 4). Pan teaches that the tissue can be attached to the coverslip, rinsed in alcohol and allowed to dry prior to PCR (pg. 5). Pan also teaches that prior to the attachment of the tissue, the coverslip can have a pre-dried adhesive on the surface of the coverslip (pg 9), or can simply be dried over night (pg. 18). Pan teaches the above methods provided a simplified method that is faster, more accurate and less expensive than previous methods of carrying out PCR (see pages 1-3).

Therefore, in view of the teachings of Pan, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Atwood so as to have dried reagents on a coverslip, in order to have achieved the benefit of providing a more efficient, accurate and less expensive method of carrying out PCR.

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Atwood et al. (USPN 5,364,790) as applied to claims 20, 22-23, 25 and 27 above, and further in view of Kuan et al. (USPN 6,181,811).

The teachings of Atwood are presented above. Specifically, Atwood teaches a concave cover slip. Atwood does not teach a coverslip comprising a barcode or text.

However, the use of barcodes or text is a well-known tool for identifying slides or coverslips of interest. For example, Kuan teaches that barcodes can be used for identification purposes in automated systems (See Figs. 8a and b and cols. 14-15).

Therefore, in view of the teachings of Kuan, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the coverslip of Atwood so as to have labeled the coverslip with a barcode or text, in order to have achieved the benefit of providing an effective means for identifying a sample in an automated system.

### **Applicant's Arguments**

Applicants argue that because Atwood "neither teaches, discloses, nor suggest a concave coverslip enclosing a known volume when placed onto a microscope slide", and neither does Pan nor Kuan, the 103 rejections should be withdrawn. (See Applicants remarks on page 5).

### **Response to Applicant's Arguments**

Applicant's arguments have been considered, but are not persuasive for the reasons set forth above. That is, because Atwood does teach and disclose a concave coverslip enclosing a known volume when placed onto a microscope slide (see above), Applicants arguments are not persuasive.

### ***Conclusion***

8. No claims are allowable.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

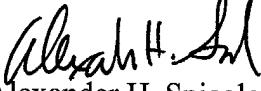
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806 or (571) 272-0788 after January 22, 2004. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (703) 308-2199 or at (571) 272-0747 after January 13, 2004. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119 or at (571) 272-0782 after January 22, 2004. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Alexander H. Spiegler  
January 5, 2004

  
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